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Maurice R. De Billot

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EXAMINER

PRYOR, ALTON NATHANIEL

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/026,301	DE BILLOT ET AL.	
	Examiner	Art Unit	
	Alton N. Pryor	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/19/07;7/16/07;4/13/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 103,106,108-110,112,117,134-145,153 and 155-158 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 103,106,108-110,112,117,134-145,153 and 155-158 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's arguments filed 6/15/07, 7/16/07 and 11/19/07 have been fully considered but they are not persuasive. The elected invention is not allowable. A restatement of final rejection dated 4/13/07 is restated. The position of the Office is similar to that of which is presented in final rejection. See discussion below.

This office action is in response to the amendments and remarks submitted on 6/15/07, 7/16/07 and 11/19/07. Claims 103,106,108-110,112,117,134-145,153 and 155-158 are pending in the application. As stated in the previous Office Action, the Examiner notes that Applicants have elected the species of agronomic plant that is soybean (glycine max), a fungicidal component that is silthiofam, an herbicidal component that is glyphosphate, and inoculating fungi that is Rhizobium spp. However, in the interests of compact prosecution, the Examiner has examined the claims to their full extent in order to apply prior art and determine the enablement of the instant claims.

Applicant's arguments regarding the rejections of the claims have been fully considered but they are not persuasive. The following rejections have been required by Applicants amendments to the claims.

Restated Office Action mailed 4/13/07:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 103,106,108-110,112,117,134-145,153 and 155-158 remain rejected under 35 U.S.C. 112, first paragraph, for lacking enablement for the full scope of the claims. The specification is enabling for a method of increasing vigor and/or the yield of a non-transgenic soybean crop by treating seeds with a combination of the particular fungicide that is silthiopham and the particular inoculant that is Bradyrhizobium spp., the specification does not reasonably provide enablement for a method of increasing the vigor and/or the yield of a legume in general, including beans, soybeans, peas, alfalfa, etc, where the plant has had a transgenic event that renders it resistant to a herbicide in general and the method includes providing a fungicide that has no significant activity against fungal plant pathogens that are associated with that plant, along with the herbicide via foliar application.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without undue experimentation. Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

1. The nature of the invention: The instant invention 15ertains to method of

increasing vigor and/or the yield of any legume that has had a transgenic even to confer resistance to any herbicide, without limitation, by providing to the plant or propagation material thereof the herbicide along with any of the numerous and diverse fungicide compounds as recited in the claim that also have the functional limitation of not being active against the pathogens of that particular plant.

2. The state of the prior art: The state of the art regarding the action of fungicides for enhancing plant growth in plants afflicted by fungi is well developed. (See for Example Seed Science, Proceedings of the International Seed Testing Association, 1981, vol. 9, pages 697-705, article by J.B. Sinclair entitled "Fungicide Sprays for the Control of Seedborne Pathogens of Rice, Soybean and Wheat.) For example it is known that fungicide sprays can be useful for controlling seedborne pathogens that afflict soybeans, as well as rice and wheat (see Summary in particular.) However, the stat of the art regarding the action of fungicides for enhancing plant growth in plants that are not afflicted by the fungi that the fungicides are known to control is not well developed. For example, the Sinclair reference teaches applying various fungicides according to the type of plant (wheat, rice, soybean) and the type of fungus afflicting the plant (see pages 699-704, in particular), and also teaches that some fungicides are also capable of controlling some of the bacteria in such plants (see Summary, in particular), but the state of the art does not indicate how fungicides could be selected to treat plants that do not harbor the fungi the fungicides are known to be effective against.

3. The predictability of the art, and the breadth of the claims: Note that the herbicidal/fungicidal art is unpredictable, requiring each embodiment to be individually

assessed for physiological activity. In re Fisher, 166 USPQ 198 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

As fungicides are typically selected on the basis of the type of plant being treated and the type of fungi pathogen that is known to afflict the plant, as shown by the Sinclair reference, it is considered that the selection of suitable fungicides that would provide enhancing effects in the absence of afflicting fungi, as well as the selection of transgenic plants that could thus be treated, and the selection of combinations of herbicides that are suitable for use therewith, is considered to be highly unpredictable.

It is furthermore noted that the recitation that the fungicide "has no significant activity against fungal plant pathogens for such agronomic plant" is considered to be functional language. Functional language at the point of novelty, as herein employed by • Applicants, is admonished in *University of California v. Eft Lilly and Co.* 43 USPQ2d 1398 (CAFC, 1997) at 1406: stating this usage does "little more than outline the goal appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate." The CAFC further clearly states that "[A] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials" at 1405 (emphasis added), and that "It does not define any structural features commonly Possessed by members of the genus that distinguish from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of

the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus ..." at 1406 (emphasis added.) Thus, claims employing functional language at the exact point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limited monopoly asserted" (General Electric Company v. Wabash Appliance Corporation et al. 37 USPQ at 468 (US Supreme Court 1938).)

4. The quantity of guidance provided and presence or absence of working examples:

The specification does not provide adequate guidance as to how one of ordinary skill in the art can reasonably select plant/fungicide combinations where the plant has pathogens that cannot be treated by the fungicide without under experimentation, and instead merely lists a number of different crops and numerous and diverse different fungicides that could be tried. With regards to working examples, the specification provides examples that show that improved vigor and/or yield is achieved the particular legume that is a soybean plant when the particular fungicide that is silthiopham is combined with the additive mollyflo and an inoculant that is Bradyrhizobium spp (see Table 1 and Table 2.) In particular, for the treatment of soybean plants, the particular combination of silthiopham + mollyflo + inoculant provides improved growth and/or vigor over treatment with just silthiopham or with just mollyflo and the inoculant. Applicants have also shown that increased yield is achieved for soybeans by treating with silthiopham and the inoculant that is Bradyrhizobium spp. (see Table 5, in particular). Thus, Applicants show that a combination of the particular fungicide that is silthiopham with the plant that is soybean (not transgenic soybean) and provided with

the inoculant *Bradyrhizobium* spp, can give enhanced growth. However, the Examiner notes that the specification does not provide any other working examples of plants other than soybeans and/or other fungicide combinations that may be suitable, and also does not provide examples of the efficacy with transgenic plants having herbicidal resistance or the use of such herbicide. The Examiner furthermore notes that the examples show improved results only for those seeds treated with both the inoculant and the silthiopham, with the seeds that have been treated only with silthiopham faring more poorly. Thus, the evidence in the examples is not commensurate in scope with the claimed invention and does not demonstrate criticality of the types of transgenic plants, fungicides and/or herbicides in the claimed method. The Examples do not provide further guidance as to how one of ordinary skill in the art could select a fungicide/transgenic plant/herbicide combination where the fungicide has no significant fungal activity, yet improves the plant vigor and/or yield in combination with the herbicide.

5. Quantity of Experimentation Necessary

In order to successfully carry out the invention, a person of ordinary skill in the art would need to first select a transgenic plant/herbicide combination from among the numerous and diverse plants and herbicides that are encompassed by the claims. After making this selection, the person would need to test the transgenic plant to determine what fungal pathogens it is host to and/or affected by, which could involve exhaustive testing for the many different types of fungal pathogens, known and unknown, that are capable of infecting various plants. After determining the pathogens that afflict the particular

plant, one of ordinary skill would need to determine which of the numerous and diverse fungicides encompassed by the claim do not have activity against the fungal plant pathogens, which would similarly involving even more testing and assays against each of the pathogens that have been found to afflict the selected transgenic plant.

Once a suitable fungicide has been identified, the fungicide would need to be tested for growth enhancement by treating the plant with various selected parameters, including a selected dosing rate, a desired inoculum, etc, and observing the plant growth.

Alternatively, a fungicide could first be selected and extensively tested to determine which pathogens it active against, after which an exhaustive search would need to be performed to find a transgenic plant/herbicide combination having the pathogens the fungicide is not active against. If improved vigor and/or yield was not achieved in the plants as grown, testing would have to be continued by either changing the plant growth conditions, by selecting a new fungicide, or by selecting a new transgenic plant/herbicide combination, and repeating the steps as set forth above. Such lengthy and arduous testing is deemed to require unnecessary and undue experimentation on the part of one of ordinary skill in the art.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for a search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of ordinary skill in the art would have

to engage in undue experimentation to test all of the transgenic legumes/herbicides/fungicides encompassed by the instant claims, with no assurance of Success.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 103-104, 106, 109-110, 112 and 134-148, 150 and 153-158 are rejected under 35 U.S.C. 103(a) as being unpatentable over the article entitled "Isolation of Gaeumannomyces Graminis var. graminis from Soybeans in the Midwest" by Roy et al, in Plant Disease, 1982, Vol. 66 No. 9, pages 822-825 in view of either U.S. Patent No. 5,486,621 to Phillion et al, issued January 23, 1996 (hereinafter Phillion et al. '621) or U.S. Patent No. 5,994,270 to Phillion et al, issued November 30, 1999 (hereinafter Phillion et al. '270) and further in view of U.S. Patent No. 5,914,451 to Martinell et al, issued June 22, 1999 and U.S. Patent No. 6,277,847 to Theodoridis et al, issued August 21, 2001.

Roy et al. teaches the isolation of Gaumannomyces graminis var. graminis from soybeans, which is the cause of take-all disease in wheat and other cereals (see abstract in particular.) Roy et al. teaches that the G. graminis fungi isolated from the

soybean was capable of infecting wheat, with discolored roots, necroses and vascular occlusion adjacent to infected cortical tissue that is typical of take-all disease, whereas disease symptoms, were not apparent on the leaves, stems or roots of the infected soybean plants (see page 824, right hand column, third full paragraph, in particular.)

Roy et al. teaches that the discovery of *G. graminis* infection in soybean plants is significant, because take-all disease is known to be frequently severe in wheat grown after soybeans, and the planting of wheat following other legumes has been reported to increase the incidence of take-all (see page 825, middle column, first full paragraph, in particular.) Roy et al. teaches that their study indicates that there is reason to suspect that the inoculum of *G. graminis* may increase through its survival on soybean tissues (see page 825, middle column, first full paragraph, in particular.) Thus, Roy et al. teaches that infection of soybean with *G. graminis* may be at least partially responsible for the heightened occurrence of take-all disease in subsequently planted wheat or cereal crops.

Roy et al. does not specifically teach providing the fungicides, herbicides or transgenic event as claimed for the treatment of the soybean.

The Phillion et al. references ('621 and '270) teach fungicides for the control of take-all disease in plants (see abstracts, in particular.) In particular, the references teach that the fungicides are effective against the soil-borne fungus *Gaeumannomyces graminis* (see abstracts, in particular.) The fungicides taught therein meet the limitations of the fungicide corresponding to the formula as recited in claim 103 (see abstracts, in particular.)

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to treat the soybean plants of Roy et al. with the fungicides as taught by the Phillion et al. references, because Roy et al. teaches that the *G. graminis* fungus infecting the soybean can be transmitted to subsequently plant wheat, which causes devastating take-all disease in the wheat, and the Phillion et al. references teach fungicides that are effective against *G. graminis*. Thus, one of ordinary skill in the art would have found it obvious to treat the soybeans with the fungicides that are effective against *G. graminis*, with the expectation of reducing the threat of the *G. graminis* to subsequently planted wheat or other cereal crops.

Roy et al. and the Phillion et al. references do not specifically teach applying an herbicide to the soybean or soybeans having had a transgenic event providing the plant with resistant to a herbicide, as recited by claim 103.

Martinell et al. teaches that it is known to transgenically modify soybean plants to render them glyphosphate tolerant, such that glyphosphates can be applied to the soybean plants as an herbicide without adversely affecting the plants (see abstract and column 3, lines 1-45, in particular.)

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the transgenic soybean and herbicide of Martinell et al. in the method of Roy et al. and the Phillion et al. references, because Roy et al. and the Phillion et al. references teach a method of growing soybean crops, while Martinell et al. teaches that improved transgenic soybeans can be provided with enhanced resistance to the herbicide glyphosphate, such that improved yields of the

soybean can be obtained. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the transgenic soybean and glyphosphate herbicide of Martinell et al. in the method of Roy et al. and Phillion et al, with the expectation of improving the yield of the soybean crop. Roy et al, the Phillion et al. references and Martinell et al. do not specifically teach foliar application of the herbicide.

Theodoridis et al. teaches that it is known to apply herbicide-containing formulas to the foliage of plants (see column 12, lines 1-5, in particular.)

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to apply herbicides to foliage, as taught by Theodoridis et al, in the methods of Roy et al, the Phillion et al. references, and Martinell et al, because Roy et al, the Phillion et al. references, and Martinell et al. teach the application of herbicides to soybean, and Theodoridis teaches that an accepted means of applying herbicides is to the foliage of the plant. Thus, one of ordinary skill in the art would have found it obvious to applying the herbicide to the foliage in the method of Roy et al, the Phillion et al. references, and Martinell et al, with the expectation of increasing the yield of the soybean crop.

Accordingly, claim 103 is obvious over the teachings of Roy et al, the Phillion et al. references, Martinell et al. and Theodoridis et al.

Regarding the recitation that the "fungicide has no significant activity against fungal plant pathogens for such agronomic plant" as in claim 103, it is noted that as the combined teachings of references renders obvious the use of the fungicide as claimed,

the property of such a claimed fungicide will also be rendered obvious by the prior art teachings, since the properties, namely the activity against fungal plant pathogens, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705,709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as that recited in the claim.

Regarding the recitation in claim 103 that the methods are for "increasing the vigor and/or the yield of an agronomic plant" as recited in the claim, it is noted that as the references render obvious providing transgenic soybean with improved resistance to the glyphosphate herbicide, and the use of the glyphosphate herbicide to improve soybean yield, it is considered that the method as taught by the references necessarily also results in increasing the vigor and/or the yield of the soybean plant.

Regarding claims 104 and 110, it is noted that Martinell et al. teaches providing transgenic soybeans with resistance to the herbicide glyphosphate, as recited in the claim. Regarding claims 106 and 112, Phillion et al. '621 teaches providing the silthiofam fungicide as claimed (see abstract, in particular.) Regarding claim 109, Theodoridis et al. teaches that herbicides can be suitably applied to foliage, as discussed above, and further teaches that such compositions applied to foliage can be formulated with fungicides (see column 12, lines 64-68, in particular.) Accordingly, it is considered that it would be obvious to one of ordinary skill in the art to apply the

fungicide and herbicide as claimed foliarly, with the expectation of success in improving the growth and/or yield of the soybean plants.

Regarding claims 134-148 and 150, the Phillion et al. references teach providing fungicides that meet the structural limitations of the claims (see abstracts, in particular.)

Regarding claims 153-155, the references teach treating soybean and even transgenic soybean, as has been discussed above. Regarding claims 156-158, it is noted that the Phillion et al. references teach that the fungicide can be provided on seed at rates of from 0.01 to 50 g per kg of seed (see column 7, lines 45-55 of Phillion et al. '270, in particular), and 25 g per 100 kg of seed (see column 13, lines 29-40 of Phillion et al. '621, in particular.) Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the composition provided on the seed, according to the guidance provided by the references, to provide a composition having desired fungicidal properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454,456, 105 USPQ 233,235 (CCPA 1955.)

Claims 108 and 117 are rejected under 35 U.S.C. 103(a) as being unpatentable over the article entitled "Isolation of Gaeumannomyces Graminis var. graminis from Soybeans in the Midwest" by Roy et al, in Plant Disease, 1982, Vol. 66 No. 9, pages 822-825 in view of either U.S. Patent No. 5,486,621 to Phillion et al, issued January 23, 1996 (hereinafter Phillion et al. '621) or U.S. Patent No. 5,994,270 to Phillion et al, issued November 30, 1999 (hereinafter Phillion et al. '270) and further in view of U.S.

Patent No. 5,914,451 to Martinell et al, issued June 22, 1999 and U.S. Patent No. 6,277,847 to Theodoridis et al, issued August 21,2001, as applied to claims 103-104, 106, 109-110, 112 and 134-148, 150 and 153-158 above, and further in view of U.S. Patent No. 4,136,486 to Franklin, Jr. et al, issued January 30, 1979.

The Roy et al., Phillion et al, Martinell et al. and Theodoris et al. references are applied as discussed above, and render obvious the instantly claimed methods comprising applying a fungicide and a herbicide to a agronomic plant having had a transgenic event, namely soybean plant.

The references do not specifically teach the step of treating the seed of the plant with one of the inoculants as recited in claims 108 and 117.

Frank, Jr. et al. teaches that the surfaces of legume seeds can be treated with symbiotic nitrogen fixing bacteria to improved plant growth (see abstract, in particular.) Frank, Jr. et al. teaches that suitable symbiotic bacteria include *Rhizobium japonicum* or *Rhizobium* sp. of the cowpea group (see column 3, lines 30-55, in particular), and that the legumes so treated can include soybean seeds, and even provides examples of such treatment (see Example I, in particular.)

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the inoculum of Frank, Jr. et al. in the method of Roy et al., the Phillion et al. references, Martinell et al. and Theodoris et al, because these references teach growing soybean agronomic crops, and Frank, Jr. et al. teaches that the growth of soybean plants can be improved by treating the seeds with the bacteria inoculums. Thus, one of ordinary skill in the art would have found it obvious

to provide the bacterial inoculums in the method of Roy et al., the Phillion et al. references, Martinell et al. and Theodoris et al, with the expectation of success in achieving improved growth of the soybean plants.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). "

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 103, 103, 106, 108-110, 112, 117, 134-145, 153 and 155-158 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 111-113, 115-117 and 122-125 of copending Application No. 11/138,965 as published in U.S. Patent Application Publication No. 2005/0233905.

Although the conflicting claims are not identical, they are not patentably • distinct from each other because the claims both recite increasing the vigor and/or yield

of a plant that has had a transgenic event by applying an herbicide and a fungicide, where the set of fungicide compounds as claimed in the instant application overlaps with those recited in the conflicting published application. Accordingly, it is considered that the overlapping fungicide compounds render the instant claims obvious over the methods recited in the conflicting application. Accordingly, claims 103-104, 106, 108-110, 112, 117, 134-148, 150, and 153-158 are not patentably distinct over claims 111-113, 115-117 and 122-125 of copending Application No. 11/138,965.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 6/15/07, 7/16/07 and 11/19/07 have been fully considered but they are not persuasive.

In particular, regarding the rejection of the claims under 35 U.S.C. 112, first paragraph, as lacking enablement for the entire scope of the claims, Applicants argue that the claims as amended are in fact fully enabled, as one of ordinary skill in the art would be able to carry out the claimed method without undue experimentation. In particular, Applicants argue that it would not require undue experimentation to carry out the claimed method to increase the vigor and/or yield of an agronomic plant that is a legume by treating with a fungicide having the chemical formula as recited in amended claim 103.

The Examiner respectfully disagrees. In particular, the Examiner notes that the claims even as amended encompass methods involving a number of different plants, such as

beans, soybeans, peas and alfalfa, and a number of different and varying fungicides having different chemical formulas that would not be expected to have the same chemical/biochemical activity or yield the same plant treatment results. The claims also encompass methods with those legume plants having any transgenic event that renders it resistant to a herbicide in general, as discussed above. While Applicants are clearly enabled for the treatment of a non-transgenic legume that is soybean with the particular fungicide that is silthiofam and the inoculant that is Bradyrhizobium spp, Applicants have not shown or provided evidence to demonstrate how one of ordinary skill in the art could expect the various other fungicide compounds encompassed by the claims to have the same vigor-enhancing properties of silthiofam, or how legumes other than soybeans could be expected to show the same vigor-enhancing benefits when treated by silthiofam. Accordingly, it is considered that one of ordinary skill in the art would have to undergo undue experimentation to test all legume plants with all of the numerous and diverse different compounds encompassed by the formula of claim 103, and in combination with various different transgenic events and herbicides, to find those combinations that yield improved vigor and/or yield, with no reasonable expectation of Success.

Applicants further cite the Declaration submitted on February 5, 2007 and signed by Ernest F. Sanders (hereinafter "Sanders Declaration"), showing silthiofam testing data on soybean crops, as evidence that the claims are fully enabled by the specification. It is noted that the claims are required to be enabled by the specification as originally filed. The Sanders Declaration is signed June 16, 2004, and thus presents data obtained at

least 2 and 1/2 years after the filing date of the instant application. Accordingly, the testing data described in the Sanders Declaration cannot be used to show enablement of the instantly claimed methods at the time of filing of the invention. It is furthermore noted that the testing from the Sanders Declaration is limited to the application of the specific fungicide that is silthiofam to the particular legume that is soybean, without specifying whether the soybean is transgenic or non-transgenic, and with the particular inoculant that is Rhizobium, and thus suffers from the same deficiencies as the working examples provided in the specification.

The office reiterates Applicants are "clearly enabled for the treatment of a non-transgenic legume that is soybean with the particular fungicide that is silthiofam and the inoculant that is Bradyrhizobium spp, Applicants have not shown or provided evidence to demonstrate how one of ordinary skill in the art could expect the various other fungicide compounds encompassed by the claims to have the same vigor-enhancing properties of silthiofam, or how legumes other than soybeans could be expected to show the same vigor-enhancing benefits when treated by silthiofam. With respect to the declaration the office reiterates presents data obtained at least 2 and 1/2 years after the filing date of the instant application. Accordingly, the testing data described in the Sanders Declaration cannot be used to show enablement of the instantly claimed methods at the time of filing of the invention. It is furthermore noted that the testing from the Sanders Declaration is limited to the application of the specific fungicide that is silthiofam to the particular legume that is soybean, without specifying whether the soybean is transgenic or non-transgenic, and with the particular inoculant that is

Rhizobium, and thus suffers from the same deficiencies as the working examples provided in the specification.” The claims are not commensurate in scope with the data provided in the working examples in the specification and declaration.

Regarding the rejections of the claims over the prior art, Applicants argue that the combination of Roy et al. and Phillion et al. does not render obvious the application of the fungicides as claimed to soybean plants. In particular, Applicants argue that Roy et al. does not even teach that *G. graminis* fungus infecting the soybean can be transmitted to subsequently planted wheat, and recite as evidence the fact that Roy et al. teaches that they have not isolated the same lobed *G. graminis* strain that they isolated from soybeans from field-grown wheat. The Examiner respectfully disagrees. As discussed above, Roy et al. clearly teaches that *G. graminis* fungi isolated from the soybean was capable of infecting wheat, even though disease symptoms were not apparent on the infected soybean plants (see page 824, right hand column, third full paragraph, in particular), and Roy et al. emphasizes that the discovery of *G. graminis* infection in soybean plants is significant, because take-all disease is known to be frequently severe in wheat grown after soybeans, and the planting of wheat following other legumes has been reported to increase the incidence of take-all (see page 825, middle column, first full paragraph, in particular.) Roy et al. teaches that their study indicates that there is reason to suspect that the inoculum of *G. graminis* may increase through its survival on soybean tissues (see page 825, middle column, first full paragraph, in particular), and thus clearly teaches that the infection of soybean with *G.*

graminis may be at least partially responsible for the heightened occurrence of take-all disease in subsequently planted wheat or cereal crop.

Accordingly, in view of the entirety of Roy et al's teachings, it is considered that Roy et al. is merely disclosing that the specific strain having the specific characteristics found to be expressed in soybean have either not yet been found in wheat, or that the specific lobed characteristic is for some reason not expressed in wheat, and not that the particular strain of *G. graminis* is not Capable of infection of wheat, as asserted by Applicants. Accordingly, it is considered that one of ordinary skill in the art would have found it obvious to treat the soybeans taught by Roy et al. with a compound known to reduce *G. graminis* infection in plants, such as those taught by Phillion et al, with the expectation of reducing the likelihood of infection of a subsequently planted wheat crop with the devastating take-all disease.

Applicants further argue that it would not have been obvious to apply the fungicide of Phillion et al. to treat the soybeans of Roy et al. that are infected with the fungus that causes take-all disease, because the fungicide is expensive and the fungus has otherwise no deleterious effect on the soybean crop. The Examiner respectfully disagrees. It is noted that Roy et al. teaches that take-all disease is frequently severe on early seeded wheat grown after soybeans (see page 825, middle column, in particular.) Accordingly, as Roy et al. teaches that wheat planted after infected soybean can be severely affected by take-all disease (with the very name "take-all" alone indicating the severity of the disease), it is considered that one of ordinary skill in the art would have found it obvious to seek out any means of eradicating the disease, such as by treating

afflicted soybean before such plants can transmit to subsequently planted wheat crops, with the expectation of lessening the damage done by the disease.

Roy et al. and Phillion et al. make obvious the instant invention. The applicants argue that the Office has cited no teaching that treating soybeans with 1) silthiofam would have any effect on *G. graminis* on soybeans, 2) silthiofam or any other pesticide has any effect on a subsequent crop and 3) an agent having activity against *G. graminis* would be expected to affect the yield and / or the vigor of the soybeans. The Office reiterates, "Roy et al. clearly teaches that *G. graminis* fungi isolated from the soybean was capable of infecting wheat, even though disease symptoms were not apparent on the infected soybean plants (see page 824, right hand column, third full paragraph, in particular), and Roy et al. emphasizes that the discovery of *G. graminis* infection in soybean plants is significant, because take-all disease is known to be frequently severe in wheat grown after soybeans, and the planting of wheat following other legumes has been reported to increase the incidence of take-all (see page 825, middle column, first full paragraph, in particular.) Roy et al. teaches that their study indicates that there is reason to suspect that the inoculum of *G. graminis* may increase through its survival on soybean tissues (see page 825, middle column, first full paragraph, in particular), and thus clearly teaches that the infection of soybean with *G. graminis* may be at least partially responsible for the heightened occurrence of take-all disease in subsequently planted wheat or cereal crop."

With respect to the double patenting rejection of claims 103,106,108-110,112,117,134-145,153 and 155-158 over U.S. Patent Application Publication No.

2005/0233905 will be maintained until all other rejections on record are overcome.

New Rejections:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 103,106,108-110,112,117,134-145,153 and 155-158 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-62 of U.S. Patent No. 5811411. Although the conflicting claims are not identical, they are not patentably distinct from each other because both USPN '411 and instant invention makes to claim to a method of applying to instant plants / crops the instant thiophene compounds in order to control disease. The USPN '411 makes claim that the disease controlled is caused by *Gaeumannomyces* sp., whereas instant claims are to the control of an agronomic plant that is not affected by Take-all disease. The

control of *Gaeumannomyces* sp. makes the Take-all disease obvious since the control of *Gaeumannomyces* sp. is directed related to Take-all disease.

Claims 103,106,108-110,112,117,134-145,153 and 155-158 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-43 of U.S. Patent No. 5994270. Although the conflicting claims are not identical, they are not patentably distinct from each other because both USPN '270 and instant invention makes to claim to a method of applying to instant plants / crops the instant thiophene compounds in order to control disease. The USPN '270 makes claim that the disease controlled is caused by *Gaeumannomyces* sp., whereas instant claims are to the control of an agronomic plant that is not affected by Take-all disease. The control of *Gaeumannomyces* sp. makes the Take-all disease obvious since the control of *Gaeumannomyces* sp. is directed related to Take-all disease.

Claims 103,106,108-110,112,117,134-145,153 and 155-158 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 5834447. Although the conflicting claims are not identical, they are not patentably distinct from each other because both USPN '447 and instant invention makes to claim to a method of applying to instant plants / crops the instant thiophene compounds in order to control disease. The USPN '447 makes claim that the disease controlled is caused by *Gaeumannomyces* sp., whereas instant claims are to the control of an agronomic plant that is not affected by Take-all disease. The control of *Gaeumannomyces* sp. makes the Take-all disease obvious since the control of *Gaeumannomyces* sp. is directed related to Take-all disease.

Claims 103,106,108-110,112,117,134-145,153 and 155-158 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-101 of U.S. Patent No. 5705513. Although the conflicting claims are not identical, they are not patentably distinct from each other because both USPN '513 and instant invention makes to claim to a method of applying to instant plants / crops the instant thiophene compounds in order to control disease. The USPN '513 makes claim that the disease controlled is caused by *Gaeumannomyces* sp., whereas instant claims are to the control of an agronomic plant that is not affected by Take-all disease. The control of *Gaeumannomyces* sp. makes the Take-all disease obvious since the control of *Gaeumannomyces* sp. is directed related to Take-all disease.

Claims 103,106,108-110,112,117,134-145,153 and 155-158 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-61 of U.S. Patent No. 5693667. Although the conflicting claims are not identical, they are not patentably distinct from each other because both USPN '667 and instant invention makes to claim to a method of applying to instant plants / crops the instant thiophene compounds in order to control disease. The USPN '667 makes claim that the disease controlled is caused by *Gaeumannomyces* sp., whereas instant claims are to the control of an agronomic plant that is not affected by Take-all disease. The control of *Gaeumannomyces* sp. makes the Take-all disease obvious since the control of *Gaeumannomyces* sp. is directed related to Take-all disease.

Claims 103,106,108-110,112,117,134-145,153 and 155-158 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over

claims 1-35 of U.S. Patent No. 5849723. Although the conflicting claims are not identical, they are not patentably distinct from each other because both USPN '723 and instant invention makes to claim to a method of applying to instant plants / crops the instant thiophene compounds in order to control disease. The USPN '723 makes claim that the disease controlled is caused by *Gaeumannomyces* sp., whereas instant claims are to the control of an agronomic plant that is not affected by Take-all disease. The control of *Gaeumannomyces* sp. makes the Take-all disease obvious since the control of *Gaeumannomyces* sp. is directed related to Take-all disease.

Claims 103,106,108-110,112,117,134-145,153 and 155-158 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-42 of U.S. Patent No. 5498630. Although the conflicting claims are not identical, they are not patentably distinct from each other because both USPN '630 and instant invention makes to claim to a method of applying to instant plants / crops the instant thiophene compounds in order to control disease. The USPN '630 makes claim that the disease controlled is caused by *Gaeumannomyces* sp., whereas instant claims are to the control of an agronomic plant that is not affected by Take-all disease. The control of *Gaeumannomyces* sp. makes the Take-all disease obvious since the control of *Gaeumannomyces* sp. is directed related to Take-all disease.

Claims 103,106,108-110,112,117,134-145,153 and 155-158 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5486621. Although the conflicting claims are not identical, they are not patentably distinct from each other because both USPN '621 and instant

invention makes to claim to a method of applying to instant plants / crops the instant thiophene compounds in order to control disease. The USPN '621 makes claim that the disease controlled is caused by *Gaeumannomyces* sp., whereas instant claims are to the control of an agronomic plant that is not affected by Take-all disease. The control of *Gaeumannomyces* sp. makes the Take-all disease obvious since the control of *Gaeumannomyces* sp. is directed related to Take-all disease.

Claims 103,106,108-110,112,117,134-145,153 and 155-158 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-82 of U.S. Patent No. 7098170. Although the conflicting claims are not identical, they are not patentably distinct from each other because both USPN '170 and instant invention makes to claim to a method of applying to instant plants / crops the instant thiophene compounds in order to control disease. The USPN '170 makes claim that the disease controlled is caused by *Gaeumannomyces* sp., whereas instant claims are to the control of an agronomic plant that is not affected by Take-all disease. The control of *Gaeumannomyces* sp. makes the Take-all disease obvious since the control of *Gaeumannomyces* sp. is directed related to Take-all disease.

Claims 103,106,108-110,112,117,134-145,153 and 155-158 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-51 of U.S. Patent No. 6992047. Although the conflicting claims are not identical, they are not patentably distinct from each other because both USPN '047 and instant inventions make to claim to a method of applying to instant plants / crops the instant thiophene compounds in order to control pests. USPN '047 does not specifically

state that the plant is not affected by Take-all disease as instantly claimed. However, it would have been inherent that the plant would not be affected by Take-all disease since both inventions require the same active step of applying thiophene compounds to the plants.

Claims 103,106,108-110,112,117,134-145,153 and 155-158 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-65 of copending Application No. 10/439152 or 20040023802. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions make to claim to a method of applying to instant plants / crops the instant thiophene compounds (simeconazole) in order to control disease. See claim 45 in USAN '151. Both inventions are to a method of increasing the vigor and / or the yield of an agronomic plant. USAN '151 does not specifically state that the plant is not affected by Take-all disease as instantly claimed. However, it would have been inherent that the plant would not be affected by Take-all disease since both inventions require the same active step of applying thiophene compounds to the plants.

This is a provisional obviousness-type double patenting rejection.

Telephonic Inquiry

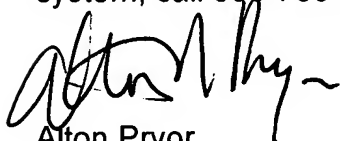
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Alton Pryor
Primary Examiner
AU 1616